DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Siemens AG Medical Solutions
% James Kuhn Jr.
Senior Regulatory Submissions Manager
20 Valley Stream Parkway
MALVERN PA 19355

May 12, 2015

Re: K143196
Trade/Device Name: syngo.CT Lung CAD
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: OEB
Dated: April 20, 2015
Received: April 22, 2015

Dear Mr. Kuhn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k143196

Device Name
syngo.CT Lung CAD

Indications for Use *(Describe)*

The syngo.CT Lung CAD device is a computer-aided detection (CAD) tool designed to assist radiologists in the detection of solid pulmonary nodules during review of multi-detector computed tomography (MDCT) examinations of the chest. The software is an adjunctive tool to alert the radiologist to regions of interest (ROI) that may have been initially overlooked. The syngo.CT Lung CAD device is intended to be used as a second reader after the radiologist has completed his/her initial read.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

This summary of 510(k) safety and effectiveness is provided in accordance with the requirements of SMDA 1990 and 21 CFR §807.92

Date Prepared: May 11th, 2015

General Information

Legal Manufacturer

Siemens AG
Medical Solutions
Henkestrasse 127
91052 Erlangen
Germany

Manufacturing Location

Siemens Medical Solutions USA, Inc.
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Malvern PA. 19355

Establishment Registration Number: 3002808157

Contact Person
James E. Kuhn Jr.
Senior Regulatory Submissions Manager
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Device Name and Classification

Trade Name:	*syngo*.CT Lung CAD
Classification Name:	Lung computed tomography system, computer-aided detection
CFR Section:	21 CFR §892. 2050
Device Class:	Class II
Product Code:	OEB

Safety and Effectiveness Information Supporting the Substantial Equivalence Determination

Device Description

*syngo.*CT Lung CAD is a medical device that is designed to perform CAD processing in thoracic CT examinations for the detection of solid pulmonary nodules ≥ 3 mm in size. The device processes images acquired with Siemens multi-detector CT scanners with 4 or more detector rows.

The *syngo.*CT Lung CAD device supports the full range of nodule locations (central, peripheral) and contours (round, irregular). The detection performance of the *syngo.*CT Lung CAD device is optimized for nodules between 3 mm and 10 mm in size. Additionally, the *syngo.*CT Lung CAD device can be used in scans with or without contrast enhancement.

The device receives images via an input data interface, performs CAD processing and provides locations of suspected nodules as an output. Specific visualization applications, such as the *syngo* PET&CT Oncology application (K093621) or equivalent Siemens products, should be used (but are not part of this clearance) to display the CAD marks. The *syngo.*CT Lung CAD device is intended to be used as a second reader only after the initial read is completed.

Intended Use

The *syngo*.CT Lung CAD device is a computer-aided detection (CAD) tool designed to assist radiologists in the detection of solid pulmonary nodules during review of multi-detector computed tomography (MDCT) examinations of the chest. The software is an adjunctive tool to alert the radiologist to regions of interest (ROI) that may have been initially overlooked. The *syngo.*CT Lung CAD device is intended to be used as a second reader after the radiologist has completed his/her initial read.

Safety and Effectiveness Information

Software design description, hazard analysis, and technical and safety information have also been completed and provided in support of this device. Risk management is ensured via the hazard analysis, which is used to identify potential hazards. These potential hazards are controlled during the development, verification/validation testing, and adherence to recognized and established industry practices and standards.

The device has no patient contacting materials and is utilized only by trained professionals. The output of the device is evaluated by trained professionals as a second reader. Use of this device does not impact the quality or status of the original acquired data.

Substantial Equivalence

The *syngo.*CT Lung CAD is substantially equivalent, both in intended use and technical characteristics to the following device:

Company	Product – Trade Name	510(k) #
Siemens	*syngo* Lung CAD	K063877

In summary, Siemens is of the opinion that the *syngo*.CT Lung CAD software, as described within this document, does not pose any unmitigated potential safety risks and is substantially equivalent to and performs as well as the predicate device.

The difference between the predicate device *syngo* Lung CAD *and syngo*.CT Lung CAD are minor in nature and both devices have the same characteristics and functionalities. The comparison table below summarizes the differences and similarities between the two devices.

Subject Device	***syngo* Lung CAD 510(k) (K063877)**	***syngo*.CT Lung CAD new version**
Differences		
Device name	*syngo* Lung CAD	*syngo*.CT Lung CAD
Platform	*syngo* classic	*syngo*.via
Similarities		
Workflow	Second reader tool	Second reader tool
Detection target	Solid pulmonary nodules in diagnostic chest CT exams	Solid pulmonary nodules in diagnostic chest CT exams
Indications For Use	The *syngo* Lung CAD device is a computer-aided detection (CAD) tool designed to assist radiologists in the detection of solid pulmonary nodules during review of multi-detector computed tomography (MDCT) examinations of the chest. The software is an adjunctive tool to alert the radiologist to regions of interest (ROI) that may have been initially overlooked. The *syngo* Lung CAD device is intended to be used as a second reader after the radiologist has completed his/her initial read.	The *syngo*.CT Lung CAD device is a computer-aided detection (CAD) tool designed to assist radiologists in the detection of solid pulmonary nodules during review of multi-detector computed tomography (MDCT) examinations of the chest. The software is an adjunctive tool to alert the radiologist to regions of interest (ROI) that may have been initially overlooked. The *syngo*.CT Lung CAD device is intended to be used as a second reader after the radiologist has completed his/her initial read.

Non-clinical Performance Testing Summary

Non-clinical tests were conducted for the device *syngo*.CT Lung CAD during product development. The modifications described in this Premarket Notification were supported with verification and validation testing.

Siemens claims conformance to the following standards:

- ISO 14971:2007: Medical Devices – Application of risk assessment to medical devices.

- IEC 62304:2006: Medical Device Software life cycle processes.

- IEC 62366:2007: Application of usability engineering to medical devices.

Software Verification and Validation

Testing, including standalone performance testing, were conducted to assess the new syngo.CT Lung CAD device and compare it to the predicate device with respect to false positives, sensitivity, and the dismissibility of false positives. The results of these tests support the substantial equivalence of this device.

The Risk Analysis was completed and risk control implemented to mitigate identified hazards. The testing results support that all the software specifications have met the acceptance criteria. Testing for verification and validation for the device was found acceptable to support the claims of substantial equivalence.

Software documentation for a Moderate Level of Concern software per FDA's Guidance Document "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*" issued on May 11, 2005 is included as part of this submission. The performance data demonstrates that the subject device conforms to the special controls for medical devices containing software.

Summary
Performance tests were conducted to test the functionality of the device *syngo.*CT Lung CAD. Results of all conducted testing were found acceptable in supporting the claim of substantial equivalence.